UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JODI ROUVIERE and ANDRE ROUVIERE, Plaintiffs, v. DEPUY ORTHOPAEDICS, INC. n/k/a MEDICAL DEVICE BUSINESS SERVICES, INC. and HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS, Defendants.	)	Case No. 1:18-cv-04814-LJL-SDA

DECLARATION OF [redacted]

I, [redacted] hereby affirm and declare under penalties of perjury that the below facts and claims are true and correct:

1. I am over the age of 18 and a citizen of the United States. I currently reside in Texas.

2. I have over 25 years of experience leading multidisciplinary failure analysis and design projects in metallurgical and materials science engineering, corrosion engineering and biomedical engineering for a variety of companies and firms. I have testified internationally as a technical expert witness in cases involving medical device, automotive, aerospace, heavy equipment, fire investigations, firearms, ammunitions, and marine applications. I am a Fellow of ASM-International, a distinguished honor in the field of metallurgical and materials science engineering. I am also a Technical Advisor Member of the Association of Firearm and Tool Mark Examiners (AFTE).

3. On or about September 18, 2020, I was retained by the Law Offices of Andre A. Rouviere to evaluate the explanted hip prosthesis systems manufactured by DePuy Orthopedics and Stryker Orthopedics to determine if the components were defective in either their manufacture, design and/or failure to adequately warn. In addition, my lab, [redacted] was also given three kidney stones removed from the plaintiff for analysis to determine the metallic chemistry content. [redacted] was tasked with performing a nondestructive evaluation of the explanted hip system and kidney stones retrieved from Ms. Jodi Rouviere.

4.. On September 21, 2020, I submitted my written report and opinion after evaluating the documentation, components, technical reports, protocols of Defendants DePuy and Stryker with respect to their medical devices and appliances, available evidence, materials and documentation related to explanted hip prosthesis systems manufactured by DePuy Orthopedics and Stryker Orthopedics.

5. On or about March 25, 2021, I received a draft supplemental report and opinion of Dr. Gannon. On reviewing Dr. Gannon's draft supplemental report and opinion, I learned for the first time the results of the examination of tissue specimens of Jodi Rouviere labeled/marked S16-15059, S17-2298 A1, and S17-2298 B1, in which Dr. Gannon states:

> **a.** "The slide labeled S16-15059 shows densely collagenized fibrous and fibroadipose tissue with abundant metal-laden macrophages (Fig 1 below)."
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> **b.** "The slide labeled S17-2298 A1 consists of densely collagenized fibrous and fibrovascular tissue with numerous metal-laden macrophages, tissue necrosis, larger metal particles consistent with titanium debris and lymphocytes (Fig 2 below). Additionally, granulomas are seen indicating a type 4 hypersensitivity reaction. The larger titanium particles were not a feature of the tissue available in my original report."

c. "Slide S17-2298 B1 shows bone and bone marrow (Fig 4 below). The bone is severely osteopenic with numerous resorptive surfaces and remodeling. The bone marrow shows trilineage maturation with no atypical features in this material." And

d. "[T]hese slides show an ongoing and severe adverse reaction to metal debris in Mrs. Rouviere that continues despite revision in her prosthesis. These changes will likely continue as the metal has been shown in this material to stay resident in the body leading to additional pain and suffering."

e. "Substantial amounts of wear debris from the Cobalt and Chromium (CoCr) from metal hip implants were released into the joint tissue environment of the synovium and surrounding capsule. This wear debris was ingested by macrophages that were present and were recruited to the local environment. The metal wear debris ingestion leads to localized cellular death and significant scarring. This necrosis is directly associated with the metal laden macrophages. These morphologic and physiologic changes led to clinical symptoms and/or findings in this case, which necessitated right hip revision surgery. Mrs. Rouviere experienced an adverse reaction to metal debris as a result of wear from metal-to-metal contact in the implanted hip components. This led to accumulation of metal wear debris in and around the implant site, causing subsequent tissue destruction, bone damage, pain and difficulty ambulating and eventually leading revision surgery."

6. Had I been provided the information contained in Dr. Gannon's supplemental report described in the preceding paragraphs of this declaration, which included Dr. Gannon's identification of titanium particles, I would have performed additional analyses of the explanted components including, but not limited to, estimating the total amount of titanium released into Mrs. Rouviere's synovium and surrounding capsule due to metal wear while implanted. Dr.

Gannon's supplemental findings and opinions included titanium, as well as cobalt and chromium, wear debris in the list of metals released into Mrs. Rouviere's body that led to tissue destruction, bone damage and pain. Had this information specific to her adverse reactions to titanium wear debris been available to me, I would have focused additional attention to those specific titanium components during my non-destructive evaluation. The results from the additional analyses would have been compared to data available in the published literature.

7. Had I been provided the information contained in Dr. Gannon's supplemental report described previously in this declaration, I would have had additional opinions concerning the source of metal debris that caused the adverse tissue reactions in Mrs. Rouviere and which specific implanted components contributed to the wear debris.

8. Based on the newly produced tissue specimens labeled S16-15059, S17-2298 A1, and S17-2298 B1, and Dr. Gannon's Supplemental Report and Opinion, my original report and opinion dated September 21, 2020, is now rendered incomplete, altered and need of modification for the reasons stated in the preceding paragraphs of this declaration.

PURSUANT TO TITLE 28 U.S.C. 1746, I, [redacted] hereby declare and affirm that the foregoing facts and claims are true and correct, done under penalties of perjury on this 26th day of March 2021.

[redacted]